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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/552,705	04/19/2000	Shiuan Chen	2124-311	4317

7590 01/10/2002

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EXAMINER
FRONDA, CHRISTIAN L

ART UNIT	PAPER NUMBER
1652	

DATE MAILED: 01/10/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/552,705	Chen et al.
Examiner	**Art Unit**
Christian L. Fronda	1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☐ Responsive to communication(s) filed on _____.

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *44-51 and 53-55* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *44-51 and 53-55* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
18) ☐ Interview Summary (PTO-413) Paper No(s). _____
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other:

DETAILED ACTION

1. The finality of the previous Office Action dated 8/13/2001 (Paper No. 9) has been withdrawn.

2. In the **AMENDMENT UNDER 37 C.F.R. 1.116** dated 11/14/01 (paper no. 10), Applicants have canceled claims 43 and 52, amended claims 44-51, and added new claims 53-55.

3. Claims 44-51 and 53-55 are under consideration in this Office Action.

Claim Rejections - 35 U.S.C. § 101

4. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

5. Claims 44-51 and 53-55 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a credible asserted utility or a well established utility.

Applicants disclose a nuclear receptor co-regulatory protein that is capable of binding to a nuclear receptor or to a nuclear receptor ligand binding domain and said nuclear receptor co-regulatory protein comprises the amino acid sequence of SEQ ID NOS: 5, 8, or 9. The specification does not specifically disclose the specific function of the nuclear receptor co-regulatory protein comprising SEQ ID NOS: 5, 8, or 9 or its relationship to any disease. It appears that the main utility of the protein is to carry out further research to identify the biological function and possible diseases associated with the nuclear receptor co-regulatory protein. Substantial utility defines a "real world" use. Utilities that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use are not substantial utility. Thus, the claimed invention has no specific or substantial asserted utility.

Applicant is referred to the revised interim guidelines concerning compliance with 35 U.S.C. 101, published in the Official Gazette and also available at www.uspto.gov.

Claim Rejections - 35 U.S.C. § 112, 1st Paragraph

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 44-51 and 53-55 are rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a credible asserted utility or a well established utility for the reasons set forth above in the rejection of claims 44-51 and 53-55 under 35 U.S.C. 101, one skilled in the art clearly would not know how to use the claimed invention.

Furthermore, the nature and breadth of the claims encompasses any chemical or any protein comprising an amino acid sequence set forth in SEQ ID NO:5 or SEQ ID NO: 9. The specification does not provide guidance in using any protein comprising SEQ ID NO: 5 or SEQ ID NO: 9 in the claimed screening method. Because the claims encompass any protein comprising SEQ ID NO: 5 or SEQ ID NO: 9, knowledge regarding the biological function, biological activity, or utility of any protein comprising SEQ ID NO:5 or SEQ ID NO: 9 is required in order to determine if the claimed protein comprising SEQ ID NO: 5 or SEQ ID NO: 9 can be used in the claimed screening method. Experimentation must be conducted to determine whether any protein comprising SEQ ID NO: 5 or SEQ ID NO: 9 can be used in the claimed screening method.

The specification does not disclose that any protein comprising SEQ ID NO:5 or SEQ ID NO: 9 interacts with nuclear receptors. Thus, an undue amount of experimentation must be conducted to determine whether any protein comprising SEQ ID NO: 5 or SEQ ID NO: 9 interacts with nuclear receptors and thus can be used in the claimed screening method. Such experimentation entails screening a vast number of organisms for a protein comprising the claimed amino acid sequences of SEQ ID NO:5 or SEQ ID NO:9, isolating the gene encoding the protein from libraries prepared from the selected organism, expressing the protein, and determining whether the protein interacts with nuclear receptors and can be used in the claimed screening method. Determining whether any protein comprising SEQ ID NO: 5 or SEQ ID NO: 9 can be used in the claimed screening method is well outside the realm of routine experimentation and predictability in the art of success is extremely low. In addition, experimentation involving screening for chemicals which promote the binding of any protein comprising SEQ ID NO: 5 or SEQ ID NO: 9 to nuclear receptors is well outside the realm of routine experimentation.

Because the specification does not teach how to use the claimed screening method with any protein comprising SEQ ID NO: 5 or SEQ ID NO: 9 and the amount of experimentation to

determine whether any protein comprising SEQ ID NO: 5 or SEQ ID NO: 9 interacts with nuclear receptors is undue, the specification does not enable any person skilled in the art to make and use the invention commensurate in scope with these claims.

8. Claims 44-51 and 53-55 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicants' arguments filed on 11/14/01 (paper no. 10), have been fully considered but they are not persuasive. Applicants argue that the specification enables one of ordinary skill in the art to perform each step of claimed method and that the claims are drawn to a method of screening for a protein which interacts with a chemical and that there is a disclosure of a structure to function/activity.

The specification, only provides the following representative species of chemicals encompassed by these claims: estradiol, dexoycorticosterone, progesterone, and retionic acid. There is no disclosure of any particular structure to function/activity relationship in the disclosed species. The chemicals encompassed by the claim are expected to differ with respect to chemical formula and chemical property. The specification also fails to describe additional representative species of these chemicals by any identifying structural characteristics or properties other than the chemical promoting the binding of the claimed co-regulatory protein and nuclear receptor or nuclear receptor ligand binding domain for which no predictability of structure is apparent. Given this lack of additional representative species of chemicals as encompassed by the claims, Applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise, and exact terms that a skilled artisan would recognize Applicants were in possession of the claimed invention.

The specification discloses that PNRC (proline-rich nuclear receptor co-regulatory protein) has an amino acid sequence of 327 amino acid residues (SEQ ID NO: 8). The amino acid sequence of SEQ ID NO: 5 which consists of seven amino acid residues was identified as a binding motif in the disclosed PNRC having the amino acid sequence of SEQ ID NO: 8. The amino acid sequence of SEQ ID NO: 9 is disclosed as consisting of 23 amino acid residues which comprises SEQ ID NO: 5.

The claims encompass any protein of any amino acid sequence which comprises SEQ ID NO: 5 or SEQ ID NO: 9. However, the specification does not provide a written description of any protein comprising SEQ ID NO: 5 or SEQ ID NO: 9 because the specific amino acid sequence that is N-terminal and C-terminal to SEQ ID NO: 5 or SEQ ID NO: 9 has not been described. The disclosed PNRC having SEQ ID NO: 8 is the single representative species of a protein comprising SEQ ID NO: 5 or SEQ ID NO: 9. The specification also fails to describe additional representative species of the claimed proteins by any identifying structural

characteristics or properties other than the protein having SEQ ID NO: 5 or SEQ ID NO: 9, for which no predictability of structure is apparent. Given this lack of additional representative species of proteins comprising SEQ ID NO: 5 or SEQ ID NO: 9 as encompassed by the claims, Applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise, and exact terms that a skilled artisan would recognize Applicants were in possession of the claimed invention.

Conclusion

9. No claim is allowed.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christian L. Fronda whose telephone number is (703)305-1252. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can be reached at (703)308-3804. The fax phone number for this Group is (703)308-0294. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703)308-0196.

CLF

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